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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,574	08/05/2003	Ramin Shiekhattar	WSTR-0014C	1505

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EXAMINER	
HOLLERAN, ANNE L	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/634,574	SHIEKHATTAR, RAMIN	
	Examiner	Art Unit	
	Anne L. Holleran	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The response the restriction requirement mailed 6/27/2006 is acknowledged. Applicants elected Group I with traverse. Upon further consideration, a new restriction requirement is set forth.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3 (in part, to the extent reads on methods comprising the use of an agent that interacts with nucleic acid sequence), drawn to methods of modulating the expression or activity of at least one component of a BRCA1-BRCA2-containing complex, classified in class 514, subclass 44.

II. Claims 1-3 (in part, to the extent reads on methods comprising the use of an agent that interacts with a protein), drawn to methods of modulating the expression or activity of at least one component of a BRCA1-BRCA2-containing complex, classified in class 424, subclass 130.1.

III. Claims 7-9, and 14 drawn to agents.

IV. Claim 10-12, and 15 drawn to method for treating cancer comprising using an agent of claims 4, 5, 6 or 13.

V. Claim 4-6, and 13, drawn to method for identifying an agents that modulate activity of BRCC or that inhibit expression of BRCC36 or BRE protein, classified in class 435, subclass 6.

VI. Claim 16, drawn to an antibody that recognizes BRCC36 or BRE protein, classified in class 530, subclass 387.1.

VII. Claim 17 (in part, to extent level of nucleic acids is detected), drawn to a method for diagnosing cancer, classified in class 435, subclass 6.

VIII. Claim 17 (in part, to extent level of a protein is detected), drawn to method for diagnosing cancer, classified in class 435, subclass 7.1.

2. The inventions are distinct each from the other, for the following reasons:

Inventions I and II are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods of group I require the use of nucleic acids, whereas the methods of group II require the use of protein. Thus, the methods are mutually exclusive and have a materially different design and mode of operation. Additionally, it would place an undue burden on the examiner to have to search and examine the two inventions together because the literature concerning methods for use of nucleic acids is not coextensive with the literature for methods of use of proteins.

Inventions VII and VIII are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods of group VII require the use of nucleic acids, whereas the methods of group VIII require the use of protein. Thus, the methods are mutually exclusive and have a materially different design and mode of operation.

Additionally, it would place an undue burden on the examiner to have to search and examine the two inventions together because the literature concerning methods for use of nucleic acids is not coextensive with the literature for methods of use of proteins.

Inventions I and IV, V, VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to different processes that have different designs and different modes of operation. In the case of group I, the claims are drawn to modulating the activity or expression of a complex, whereas the methods of groups IV, V, VII and VIII are drawn to methods of treating cancer, methods for identifying agent that inhibits expression or activity of BRCC36 or BRE, methods for diagnosing cancer where levels of nucleic acids are detected, and methods for diagnosing cancer were levels of protein are detected, respectively. Thus, the search of the different groups would not be coextensive because different steps and reagents would need to be searched in the Patent and non-patent literature. As such, the search and examination of more than one of the groups would place an undue burden on the examiner.

Inventions II and IV, V, VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to different processes that have different designs and different modes of operation. In the case of group II, the claims are drawn to modulating the activity of a complex, whereas the methods of groups IV, V, VII and VIII are drawn to methods of treating cancer, methods for identifying agent that inhibits expression or activity of BRCC36 or BRE, methods

for diagnosing cancer where levels of nucleic acids are detected, and methods for diagnosing cancer were levels of protein are detected, respectively. Thus, the search of the different groups would not be coextensive because different steps and reagents would need to be searched in the Patent and non-patent literature. As such, the search and examination of more than one of the groups would place an undue burden on the examiner.

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the inventions of group III, the claims are drawn to agents that modulate the activity or expression of either the nucleic acid or protein product of a BRCA1-BRCA2 complex, whereas the inventions of group V are drawn to methods for identifying agents that modulate activity of BRCC or that inhibit expression of BrCC36 or BRE protein. The methods of group V neither use nor make the agents of group III. Additionally, these agents are described only in functional terms. Thus, the search of the different groups would not be coextensive because different steps and reagents would need to be searched in the Patent and non-patent literature based on a function and not on a structure. As such, the search and examination of more than one of the groups together would place an undue burden on the examiner.

Inventions III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to different processes that have different designs and different modes of operation. In the case of group III, the claims are drawn to agents that modulate the activity or expression of either

the nucleic acid or protein product of a BRCA1-BRCA2 complex, whereas the products of group VI are drawn to antibodies that recognize BRCC36 or BRE protein. Additionally, these agents are described only in functional terms. Thus, the search of the different groups would not be coextensive because different steps and reagents would need to be searched in the Patent and non-patent literature based on a function and not on a structure. As such, the search and examination of more than one of the groups together would place an undue burden on the examiner.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, there are multiple methods for treating cancer that rely on materially different products. Furthermore, the agents may be used in in vitro methods of modulating BRCA1-BRCA2 complexes. Therefore, the inventions are distinct. Because of the breadth of scope for the agents of group III, it would place an undue burden on the examiner to search and examine groups III and IV together.

Inventions VI and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, there are multiple methods for treating cancer that rely on materially different products. Furthermore, the agents may be used in in vitro methods of

inhibiting the expression of BRCC36 or BRE. Therefore, the inventions are distinct. Because of the breadth of scope for the agents of group VI, it would place an undue burden on the examiner to search and examine groups VI and VII together.

4. In re Ochiai:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to

retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
September 27, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER